NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PERRIGO COMPANY, *et al.*, Plaintiffs, v. ABBVIE INC., *et al.*, Defendants.	Case No. 2:20-cv-17560 (BRM) (ESK) **OPINION TEMPORARILY FILED UNDER SEAL**

MARTINOTTI, DISTRICT JUDGE

Before this Court is Defendants AbbVie Inc. ("AV Inc."), Abbott Laboratories ("Abbott") (together, "AbbVie"), Unimed Pharmaceuticals, LLC ("Unimed"), and Besins Healthcare, Inc.'s ("Besins" and, with AbbVie and Unimed, "Defendants") Motion for Judgment on the Pleadings. (ECF No. 70.) Plaintiffs Perrigo Company ("Perrigo Co."), Perrigo Israel Pharmaceuticals Ltd. ("Perrigo Israel"), and Perrigo Company of South Carolina, Inc. ("Perrigo S.C.") (collectively, "Perrigo") opposed (ECF No. 76), and Defendants replied (ECF No. 79). Having reviewed the parties' submissions filed in connection with the Motion and having held oral argument pursuant to Federal Rule of Civil Procedure 78(a) on September 15, 2021 (*see* ECF Nos. 92, 93), for the reasons set forth below and for good cause shown, Defendants' Motion for Judgment on the Pleadings is **GRANTED**.

I. BACKGROUND

A. Parties

Perrigo Co. is a Michigan corporation that manufactures and sells health care products in the United States. (ECF No. 1 ¶ 4.) Perrigo Israel and Perrigo S.C. are Israeli and Michigan

corporations, respectively, and subsidiaries of Perrigo Co. (*Id.* ¶¶ 5–6.) Perrigo Israel "develops, manufactures and markets generic pharmaceuticals" (*id.* ¶ 5), while Perrigo S.C. effectuates their sale (*id.* ¶ 6).

Abbott is an Illinois corporation that "develops, manufacturers and markets a variety of healthcare and pharmaceutical products in the United States." (*Id.* ¶ 7.) "On January 1, 2013, Abbott completed the spinoff of [AV Inc.], a [Delaware] corporation [with an Illinois principal place of business] formed to hold Abbott's branded pharmaceutical business . . . ." (*Id.* ¶¶ 7–8.) Since this spinoff, AV Inc. "has been engaged in the manufacture, sale and distribution of branded pharmaceutical products." (*Id.* ¶ 8.) Unimed is a Delaware corporation with an Illinois principal place of business and AbbVie subsidiary. (*Id.* ¶ 9.) Besins is a Delaware corporation with a Virginia principal place of business that manufacturers AndroGel, the drug at issue in this matter, for AbbVie under a licensing agreement. (*Id.* ¶ 10.)

B. Statutory Background

"[T]he regulatory scheme that governs the testing and approval of new drugs in the United States" was established by the Hatch-Waxman Act ("Hatch-Waxman"), 21 U.S.C. § 355. *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 143 (3d Cir. 2017). Under Hatch-Waxman, a drug company can obtain Food and Drug Administration ("FDA") approval in one of three ways. "First, a drug manufacturer[] wishing to market a new prescription drug[] must submit a New Drug Application" ("NDA") to the FDA "and undergo a long, comprehensive, and costly testing process, after which, if successful, the manufacturer will receive marketing approval." *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (citing 21 U.S.C. § 355(b)(1)). "In addition to extensive testing and safety information concerning the drug, the manufacturer must also submit the patent number and expiration date of any patent that claims the drug or a method of using the drug with respect to which a claim of patent infringement could reasonably be

asserted." *Eisai Co. v. Mut. Pharm. Co.*, Civ. A. No. 06-3613, 2007 WL 4556958, at *1 (D.N.J. Dec. 20, 2007) (citing U.S.C. § 355(b)(1)). If an applicant's NDA is approved by the FDA, the patent information filed in connection with the NDA is published in the FDA's publication known as the "Orange Book." *Id.*

Second, to further its goal of "increas[ing] competition between generic and brand-name drugs," Hatch-Waxman "allows the manufacturers of generic drugs to obtain FDA approval without having to endure the gauntlet of procedures associated with NDAs." *In re Wellbutrin*, 868 F.3d at 143. Generic manufacturers may file an Abbreviated New Drug Application ("ANDA") "specifying that the generic has the 'same active ingredients as,' and is 'biologically equivalent' to, the already-approved brand-name drug." *Actavis*, 570 U.S. at 142 (quoting *Caraco Pharm. Laboratories, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012)). An ANDA allows a generic manufacturer to "avoid[] the 'costly and time-consuming studies' needed to obtain approval 'for a pioneer drug,'" thereby furthering competition. *Id.* (quoting *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990)).

Third, a generic manufacturer may also submit a Section 505(b)(2) NDA, which "is appropriate for a company seeking to modify another company's brand-name drug." *F.T.C. v. AbbVie Inc.*, 976 F.3d 327, 339 (3d Cir. 2020); *see also* 21 C.F.R. § 314.54(a) (providing that examples of a brand-name drug modification may include "a new indication or new dosage form"). A Section 505(b)(2) NDA "is like an ANDA because the company need not produce all safety and efficacy data about the drug and because it must assure the FDA that its generic drug will not infringe the brand's patents," but differs "because the company must produce some data, including whatever 'information [is] needed to support the modification(s).'" *Id.* (quoting 21 C.F.R. § 314.54(a)).

"In addition to streamlining the drug approval process, the Hatch-Waxman Act provides specialized procedures for brand-name and generic drug manufacturers to resolve intellectual property disputes." *In re Wellbutrin*, 868 F.3d at 144. Brand-name manufacturers are required to list in its NDA "the 'number and the expiration date' of any relevant patent." *Actavis*, 570 U.S. at 143 (quoting 21 U.S.C. § 355(b)(1)). Generic manufacturers, on the other hand, must assure their products will not infringe upon the brand-name's patents, which is known as a "paragraph IV notice." *AbbVie*, 976 F.3d at 339; *see also* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (certifying "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted"). After receiving a paragraph IV notice, a brand-name manufacturer has forty-five days to decide whether to sue the generic manufacturer for patent infringement. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If it decides to sue within forty-five days, the brand-name manufacturer "is rewarded with some breathing space before competition can begin: the FDA is required to withhold approval of the generic drug for 30 months or until the infringement case is resolved, whichever comes first." *In re Wellbutrin*, 868 F.3d at 144 (citing 21 U.S.C. § 355(j)(5)(B)(iii)).

Finally, if a generic drug is approved by the FDA, an applicant may request a therapeutic equivalent ("TE") rating for the drug. *AbbVie*, 976 F.3d at 340. Generic products therapeutically equivalent to the brand-name drug are assigned 'A' or 'AB' ratings, while those "for which therapeutic equivalence cannot be determined are assigned a 'B' or 'BX' rating." *Id.* (internal quotation marks and citation omitted).

C. Factual Background

"AndroGel is a brand-name transdermal testosterone gel product approved by the FDA for the treatment of hypogonadism, a clinical syndrome that results from failure of a man's body to produce adequate amounts of testosterone." (ECF No. 1 ¶ 25.) "AndroGel comes in two strengths:

(1) 1%, which was the original formulation launched in June 2000; and (2) 1.62%, which was first sold in May 2011." (*Id.* ¶ 28.) AndroGel 1% was created by Unimed and subsidiaries of Besins's parent company, Solvay. (*Id.* ¶ 29.) In 2003, Unimed and Besins filed a patent application for AndroGel 1% that claimed a penetration enhancer of isopropyl myristate. (*Id.* ¶ 34.) The patent was subsequently issued on January 7, 2003 (*id.*) and included in the FDA's Orange Book (the "'894 Patent") (*id.* ¶ 31).

Perrigo sought to enter the hypogonadism treatment market and, in December 2008, submitted two ANDAs for a generic testosterone gel. (*Id.* ¶ 35.) Perrigo's generic product, however, "contained isostearic acid as its penetration enhancer rather than [the] isopropyl myristate claimed in the" '894 Patent. (*Id.*) In June 2009, Perrigo served Unimed and Besins with paragraph IV notices asserting the generic product would not infringe upon the '894 Patent because of the different chemical makeup of the drugs' respective penetration enhancers. (*Id.* ¶ 36.) "Perrigo also stated in its notices that the prosecution history of the '894 [P]atent would estop Unimed and Besins from asserting patent infringement under the doctrine of equivalents." (*Id.*) In July 2009, Unimed, Besins, and Solvay determined they would not file patent infringement suits against Perrigo. (*Id.* ¶ 38.)

On August 26, 2009, after becoming aware of cases involving accidental secondary exposure to children, "the FDA directed that any application for a generic testosterone gel product containing a penetration enhancer different from the referenced brand-name drug would be required to be submitted as a [S]ection 505(b)(2) NDA rather than an ANDA." (*Id.* ¶¶ 39–40.) In February 2010, AbbVie acquired Solvay and Unimed, and with them, AndroGel 1%. (*Id.* ¶¶ 29,

41.) On April 9, 2010, AbbVie filed a citizen petition with the FDA,[1] seeking, *inter alia*: (1) an "assurance from the FDA that Perrigo would be required to resubmit its ANDAs referencing AndroGel 1% as [S]ection 505(b)(2) NDAs"; and (2) a directive that Perrigo provide new paragraph IV notices to the AndroGel 1% patent holders. (*Id.* ¶ 42.) On October 4, 2010, the FDA granted AbbVie's petition in relevant part, declaring: (1) "any application by a generic manufacturer for a product referencing AndroGel 1% that contained a different penetration enhancer must be submitted as a [S]ection 505(b)(2) NDA" and directing (2) any applicants to submit new paragraph IV notices. (*Id.* ¶ 43.)

On January 13, 2011, Teva Pharmaceuticals USA, Inc. ("Teva") filed a Section 505(b)(2) NDA for a generic version of AndroGel 1% with an isopropyl palmitate penetration enhancer. (*Id.* ¶ 44.) On March 16, 2011, Teva submitted to Solvay, AbbVie, Unimed, and Besins a paragraph IV notice asserting its generic drug did not infringe upon the '894 Patent. (*Id.* ¶ 45.) Teva also "laid out the prosecution history of the '894 [P]atent and its position that, because the claims of the '894 [P]atent were narrowed to disclose only isopropyl myristate, the prosecution history estops the patentees from asserting infringement under the doctrine of equivalents." (*Id.* (internal quotation marks omitted).) However, on April 29, 2011, within forty-five days of receiving Teva's paragraph IV notice, AbbVie, Unimed, and Besins commenced an action in the District of Delaware alleging infringement of the '894 Patent. (*Id.* ¶ 47.) "The suit against Teva triggered the Hatch-Waxman automatic stay of FDA approval of the Teva product" and, "[c]onsequently, the

[1] "Federal regulations provide that an interested person may petition the FDA to 'issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative actions.'" *In re Wellbutrin XL Antitrust Litig.*, Civ. A. No. 08-2431, 2012 WL 1657734, at *2 (E.D. Pa. May 11, 2012) (quoting 21 C.F.R. § 10.25). "Within 180 days of receiving the petition, the FDA must furnish a response to the petitioner either approving, denying, or providing a tentative response that indicates why the agency has been unable to reach a decision on the petition." (*Id.* (citing 21 C.F.R. § 10.30(e)(2)).

FDA could not approve Teva's generic testosterone drug for 30 months after March 16, 2011 or until September 17, 2013 unless a district court ruling or a settlement resolved the lawsuit sooner." (*Id.*)

On July 4, 2011, Perrigo re-filed its application as a Section 505(b)(2) NDA. (*Id.* ¶ 52.) On September 20, 2011, Perrigo sent AbbVie, Unimed, and Besins a new paragraph IV notice asserting no patent infringement because its generic product did not contain the same amount of isopropyl as the penetration enhancer claimed in the patent. (*Id.* ¶ 53.) However, on October 31, 2011, AbbVie, Unimed, and Besins filed suit, this time in the District of New Jersey, claiming infringement of the '894 Patent (the "AndroGel 1% Litigation"). (*Id.* ¶ 55.) The AndroGel 1% Litigation again triggered a thirty-month stay under the Hatch-Waxman Act, thereby precluding Perrigo from obtaining final FDA approval "until or about March 20, 2014" absent a court ruling or settlement resolving the matter. (*Id.*)

On December 8, 2011, Perrigo and AbbVie "executed a binding term sheet[] which included the dismissal of" the AndroGel 1% Litigation and $2 million dollars to Perrigo for "reasonable litigation expenses" (the "Settlement Agreement"). (*Id.* ¶ 58.) Furthermore, the parties agreed Perrigo could launch its product on January 1, 2015. (*Id.* ¶ 59.) On December 20, 2011, Teva and AbbVie reached a final settlement in their litigation whereby "Teva received a license to launch its product beginning December 27, 2014." (*Id.* ¶ 57.)[2]

The FDA approved Teva and Perrigo's Section 505(b)(2) NDAs on February 14, 2012 and January 31, 2013, respectively. (*Id.* ¶¶ 62–63.) Teva, however, did not receive an AB rating for its

[2] Perrigo's settlement with AbbVie also "contained an acceleration clause and most favored nations . . . protection whereby Perrigo would be permitted to launch if another generic came to market or if Defendants entered an agreement with another generic providing an entry date more favorable than the date applicable to Perrigo." (*Id.* ¶ 59.) Therefore, "[a]s a result of the Teva settlement, Perrigo's licensed entry date was moved up to December 27, 2014." (*Id.* ¶ 61.)

product from the FDA and, accordingly, "decided not to launch its generic AndroGel 1% product on the date permitted in its settlement agreement, *i.e.*, December 27, 2014 or thereafter." (*Id.* ¶ 62.) The FDA did not provide Perrigo with a TE rating in its approval letter. (*Id.* ¶ 63.) Later, "[a]s its December 27, 2014 licensed entry date approached, Perrigo took a number of steps to follow up with the FDA regarding its TE rating," including sending "three letters to the FDA between April 2013 and February 2014 requesting that the FDA issue an AB rating." (*Id.* ¶ 64.) Perrigo, however, "received no response other than being informed that the FDA needed more time to evaluate the therapeutic equivalence of the product." (*Id.*)

Perrigo subsequently filed a lawsuit against the FDA on March 21, 2014, in the District of Columbia alleging unreasonable delay and requesting "a mandatory injunction compelling the FDA to publish a TE rating for Perrigo's NDA product as soon as possible." (*Id.* ¶ 65.) In its response, the FDA maintained Perrigo's settlement with AbbVie "obviated the need for a prompt decision" and assured the court a TE rating would be issued by July 31, 2014. (*Id.*) On July 23, 2014, "[t]he FDA determined that Perrigo's Section 505(b)(2) NDA product was therapeutically equivalent to AndroGel 1% and issued it an AB rating." (*Id.* ¶ 66.) On December 27, 2014, Perrigo launched its generic version of AndroGel 1%. (*Id.* ¶ 67.)

D. Complaint and Procedural History

Perrigo filed the present action against Defendants on May 4, 2020, in the Eastern District of Pennsylvania. (ECF No. 1.) On October 21, 2020, the Honorable Harvey Bartle III, U.S.D.J. granted Defendants' motion to transfer the matter to this Court. (ECF No. 34.)

Perrigo asserts "[t]he patent lawsuits brought against both Teva and [itself] in 2011 were objectively baseless" because "[n]either the Teva product nor the Perrigo product contained the penetration enhancer isopropyl myristate, the only penetration enhancer claimed in the '894 [P]atent." (ECF No. 1 ¶¶ 69–70 (noting that "Teva used isopropyl palmitate and Perrigo used

isostearic acid as a penetration enhancer in their generic versions of AndroGel 1%").) Perrigo also maintains the patent lawsuits against Teva and itself were "subjectively baseless" because they were "filed . . . only for the purpose of delaying Teva's and Perrigo's entry into the market as competitors with lower price generics, [and] not with any expectation of actually winning the either case." (*Id.* ¶ 72.) According to Perrigo, Defendants "were aware that the entry of generic versions of AndroGel, with their much lower prices, would quickly and significantly erode" the hundreds of millions of dollars in sales Defendants took in every year. (*Id.* ¶ 77.) Defendants, accordingly, "were able to maintain monopoly power" over the topical testosterone replacement therapies market. (*Id.* ¶ 79; *see generally id.* ¶¶ 79–87.)

Perrigo alleges Defendants violated Section 2 of the Sherman Act, 15 U.S.C. § 2. (*Id.* ¶¶ 95–100.) Perrigo maintains Defendants, "[t]hrough their sham [AndroGel 1% Litigation] against Perrigo," have "willfully maintained their monopoly power in the relevant market using restrictive or exclusionary conduct," and have "substantially harmed competition . . . by delaying and/or minimizing the success of competition from a generic version of AndroGel 1%." (*Id.* ¶¶ 97–98.) In other words, Perrigo contends, "[b]ut for Defendants' anticompetitive conduct . . . , Perrigo would have received its AB rating in June 2013 rather than July 2014 and would have launched its AB-rated product at that time rather than on December 27, 2014." (*Id.* ¶ 68.)

On January 14, 2021, Defendants filed the present Motion for Judgment on the Pleadings. (ECF No. 70.) On February 16, 2021, Perrigo opposed (ECF No. 76), and on March 8, 2021, Defendants replied (ECF No. 79). On September 15, 2021, the Court heard oral argument on Defendants' Motion. (*See* ECF Nos. 92, 93.)

II. LEGAL STANDARD

"The difference between Rules 12(b)(6) and 12(c) is purely procedural as [Rule] 12(c) requests for dismissal are governed by the same standards as [Rule] 12(b)(6) motions." *Glob. Naps,*

Inc. v. Bell Atl.-N.J., Inc., 287 F. Supp. 2d 532, 539 (D.N.J. 2003) (citing *Turbe v. Gov't of the V.I.*, 938 F.2d 427, 428 (3d Cir. 1991)). As with a Rule 12(b)(6) motion, in deciding a Rule 12(c) motion, the court must "view[] the facts alleged in the pleadings and the inferences to be drawn from those facts in the light most favorable to the" nonmovant. *Barnard v. Lackawanna Cnty.*, 696 F. App'x 59, 61 (3d Cir. 2017) (internal quotation marks and citations omitted). A court may only grant a motion for judgment on the pleadings if the moving party "clearly establishes that no material issue of fact remains to be resolved and that [the movant] is entitled to judgment as a matter of law." *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008) (quoting *Jablonski v. Pan Am. World Airways, Inc.*, 863 F.2d 289, 290–91 (3d Cir. 1988)).

III. DECISION

A. Accrual of Perrigo's Claim

Defendants argue "Perrigo's current sham claim is barred by the parties' 2012 Settlement Agreement, in which Perrigo released 'any and all claims . . . accruing prior to the Effective Date . . . arising out of, related to, or in connection with . . . the [AndroGel 1%] Litigation.'" (ECF No. 70-1 at 8 (quoting ECF No. 70-6 § 7).) Defendants maintain "[t]he claim here 'arises out of' and 'relates to' the AndroGel 1% [Litigation] because the entire theory of the claim is that the AndroGel 1% [Litigation] was a sham." (*Id.*) Because, according to Defendants, a sham litigation claim accrues upon the filing of the sham lawsuit (*id.* at 9 (citations omitted)), Perrigo released such a claim when it settled the AndroGel 1% Litigation and, accordingly, may not now move forward with the present lawsuit (*id.* at 14).

The Settlement Agreement contains the following release:

> In settlement of the Litigation, and in consideration of the releases, representations, warranties and covenants contained in this . . . Agreement[,] . . . as of the Effective Date, the respective Parties and parents, subsidiaries, Affiliates, related companies and predecessors, successors and assigns . . . hereby fully, finally and forever release, relinquish, acquit and discharge the other Parties . . .

> *from any and all claims*, demands, damages, liabilities, obligations, and causes of action *accruing prior to the Effective Date . . . arising out of, related to, or in connection with: (i) the Litigation . . . .*

(ECF No. 70-6 § 7 (emphasis added).)[3] The term "Effective Date" is the "date on which [the Settlement Agreement] Term Sheet [was] executed by the latest-signing party." (ECF No. 70-5 at 1–2.) The parties both concede this date was March 27, 2012. (*See* ECF No. 70-1 at 3; ECF No. 76 at 1–2; *see also* ECF No. 70-6 at 14.) The term "Litigation" refers to the AndroGel 1% Litigation, filed in the District of New Jersey by AbbVie, Unimed, and Besins against Perrigo in 2011 for the alleged infringement upon the '894 Patent. (ECF No. 70-5 at 2.)

"In New Jersey, a signed release carries considerable weight." *Cooper v. Borough of Wenonah*, 977 F. Supp. 305, 311 (D.N.J. 1997).

> It is the general rule that where a party affixes [its] signature to a written instrument, *such as a release*, a conclusive presumption arises that [it] read, understood and assented to its terms and [it] will not be heard to complain that [it] did not comprehend the effect of [its] act in the signing.

Id. at 311–12 (citations omitted). Here, both parties agree they freely entered into the Settlement Agreement and its release. (*See, e.g.*, ECF No. 1 ¶ 58 ("On December 8, 2011 the parties executed a binding term sheet, which included the dismissal of claims."); ECF No. 70-1 at 3 ("The parties settled the case on December 8, 2011, initially memorializing that settlement with a binding term sheet."); *see also* ECF No. 70-6 at 13–14 (providing the signatures of AbbVie, Unimed, Besins,

[3] "In deciding a motion for judgment on the pleadings, the court 'considers only the [pleadings], any attached exhibits, documents relied upon in the complaint, matters of public record, and any indisputably authentic documents.'" *Republic Franklin Ins. v. Travelers Cas. Ins. Co. of Am.*, Civ. A. No. 17-4593, 2018 WL 1420495, at *2 (D.N.J. Mar. 22, 2018) (quoting *Hlista v. Safeguard Props., LLC*, 649 F. App'x 217, 218 n.2 (3d Cir. 2016)). Because Perrigo's Complaint relies upon the parties' Settlement Agreement in support of its sham litigation allegation (ECF No. 1 ¶¶ 58–60, 67), and because the authenticity of the Settlement Agreement is not in dispute, the Court considers the Settlement Agreement, attached to Defendants' present motion (ECF Nos. 70-5, 70-6), when deciding this matter.

and Perrigo representatives to the Settlement Agreement).) Moreover, the parties do not appear to dispute the present sham litigation claim relates to the AndroGel 1% Litigation in a way envisioned by the Settlement Agreement and its release. (*See generally* ECF Nos. 70-1, 76, 79.) Therefore, the validity and scope of the Settlement Agreement's release is not at issue. Rather, the parties disagree over whether Perrigo's sham litigation claim accrued prior to March 27, 2012, thereby triggering the release and precluding the present lawsuit.

1. Antitrust Injury

"In order to maintain an antitrust suit, a plaintiff must establish antitrust standing, which is distinct from Article III standing." *In re Wellbutrin*, 868 F.3d at 163. "To establish antitrust standing, a plaintiff must show that it has suffered an antitrust injury—that is, an 'injury of the type the antitrust laws were intended to prevent and that flows from that which makes [the] defendants' acts unlawful.'" *Id.* at 164 (quoting *Ethypharm S.A. France v. Abbott Laboratories*, 707 F.3d 223, 233 (3d Cir. 2013)).

Defendants argue, *inter alia*, Perrigo had a "sufficient basis to allege antitrust injury as soon as the alleged sham patent suit [was] filed." (ECF No. 70-1 at 12.) According to Defendants, the thirty-month stay pursuant to Hatch-Waxman precluding earlier FDA approval of Perrigo's generic product established an adequate antitrust injury. (*Id.* at 12–13.) Defendants cite to two opinions from this District, *Bristol-Myers Squibb Co. v. Ben Venue Laboratories*, 90 F. Supp. 2d 540 (D.N.J. 2000) and *Warner Lambert Co. v. Purepac Pharmaceutical Co.*, Civ. A. No. 98-2749, 2000 WL 34213890 (D.N.J. Dec. 22, 2000), in support of this position. (*Id.*)

In *Bristol-Myers*, the manufacturer of an anti-cancer drug filed patent infringement suits against generics after they filed ANDAs. 90 F. Supp. 2d at 541, 544. The generics filed counterclaims against the manufacturer "for monopolization and attempted monopolization in violation of Section 2 of the Sherman Act." *Id.* at 541. The manufacturer asserted the generics

failed to demonstrate the antitrust injury necessary to set forth their counterclaims because they had not yet obtained FDA approval of their drugs and, therefore, "have not lost sales due to [the manufacturer's] conduct." *Id.* at 543. According to the manufacturer, "the cause of [the generics'] injuries [could not] be [the manufacturer's] alleged misconduct—instead, the generics are barred from the market by their independent failure to secure agency approval." *Id.* at 544.

The court disagreed, finding the manufacturer's "argument ignore[d] the reality of Hatch-Waxman." *Id.* at 545. The court held there was "no dispute that by suing the generic defendants under the Hatch-Waxman Act, [the manufacturer] provoked the automatic moratorium of FDA approval of the generics' ANDAs." *Id.* For the manufacturer "to insist that its generic competitors ha[d] no standing because they [were] not in the market, when [the manufacturer] itself foreclosed their access to it," was, according to the court, without merit. *Id.* Moreover, the court noted, if it were to accept the manufacturer's position, "antitrust standing under the Hatch-Waxman Act would be wholly contingent on the vagaries of the timing of [FDA] action" and would bind claimants "to circumstances beyond their control." *Id.* at 545–46. "Such an anomalous and arbitrary result," according to the court, "was not intended by the statute." *Id.* at 545. Accordingly, the court found to establish antitrust injury and invoke antitrust standing, "a Hatch-Waxman defendant subject to the moratorium need not demonstrate that the FDA has first approved its product." *Id.* at 546.

Similarly, in *Warner Lambert*, the manufacturer of epilepsy and neurodegenerative disease drugs filed an infringement lawsuit against a generic following its ANDA. 2000 WL 34213890, at *4. The generic filed a sham litigation counterclaim, asserting the manufacturer "initiated the patent infringement litigation for the sole purpose of forestalling [the generic's] ability to enter the [drug's] market." *Id.* at *5. The court, relying in part on *Bristol-Myers*, rejected the manufacturer's argument that the generic did not have standing to assert an antitrust injury. The court determined

antitrust injury under Hatch-Waxman must be "liberally construed," *id.* at *8 ("Consequently, the Supreme Court's requirement for a special 'causal connection' and 'directness' of injury must be liberally construed when dealing with regulatory conditions under the Hatch-Waxman Act."), and held the generic's injury did "not merely result from the 'structure of a regulated industry,' but from the decision of the pioneer manufacturer to bring suit." *Id.* (quoting *Bristol-Myers*, 90 F. Supp. 2d at 545).

Perrigo's opposition did not address *Bristol-Myers*, *Warner Lambert*, or Defendants' argument that its imposition of the Hatch-Waxman thirty-month moratorium constituted actionable antitrust injury. (*See generally* ECF No. 76 at 13–15.) However, at oral argument, Perrigo maintained *Bristol-Myers*, decided in 2000, is irrelevant. (ECF No. 93 at 27:19-25.) Moreover, Perrigo cited to *In re Wellbutrin*, a recent Third Circuit opinion, in support of the position that "to show antitrust injury, the plaintiff must allege injury that impacts the competitive market. Merely showing injury to the plaintiff alone is not enough."[4] (*Id.* at 20:3-6.) The Court, however, finds Perrigo's argument misplaced and finds *In re Wellbutrin* to be distinguishable from the present facts.

In *In re Wellbutrin*, the brand-name manufacturers, Biovail and GSK, of an antidepressant drug filed patent infringement suits against two generic companies, Anchen and Abrika, triggering Hatch-Waxman's thirty-month stay. 868 F.3d at 145. Later, a class of direct and indirect purchasers of the antidepressant brought a lawsuit against Biovail and GSK, alleging, *inter alia*, the lawsuits against Anchen and Abrika amounted to sham litigations. *Id.* at 146. The purchasers argued, without the thirty-month stay and subsequent delay in ANDA approvals, the "generics would have launched their products sooner, resulting in increased competition and lower drug

[4] Perrigo did not cite to *In re Wellbutrin* in its opposition brief. (*See generally* ECF No. 76.)

prices for pharmacies and consumers." *Id.* at 147. Affirming the district court's grant of summary judgment in favor of GSK,[5] the Third Circuit determined "[t]he sham litigation claim . . . fail[ed] for the simple reason that an act of infringement plainly occurred." *Id.* at 149; *see also id.* at 152. Moreover, and importantly for the purposes of the present matter, the court held the purchasers could not establish antitrust injury because, at the time of the allegedly sham litigation, any delay in the generics' entry into the market was due to Biovail, not GSK, the remaining defendant. *Id.* at 152. The court's reasoning stemmed from the fact that, four months following the filing of the patent infringement case, GSK withdrew from the case. *Id.* at 152 n.24. The court, accordingly, held the purchasers "must show that at least some delay [could have been] attributed to GSK's actions in the case—that is, they must [have] show[n] that at least some delay can be attributed to the first four months of the litigation." *Id.* Because there was "no evidence in the record indicating that any delay [could] be linked to that period of time," *id.*, the court determined "any delay attributable to the litigation would have existed even without GSK's involvement." *Id.* at 152. Finally, the court noted the generics' entry into the market was also blocked by a patent entirely separate from GSK and Biovail.[6] *Id.* at 165. Here, the facts of *In re Wellbutrin* are not applicable. According to pleadings, it was Defendants' filing of the AndroGel 1% Litigation—not any additional defendants, patents, or exclusivity periods—that prevented Perrigo's entry into the testosterone market. (*See generally* ECF No. 1.)

[5] "Biovail was originally a defendant in the case but settled with [the purchasers] prior to the appeal." *Id.* at 142 n.2.

[6] The court further rejected the purchasers' sham litigation claims because Abrika's entry into the market was also prevented by the 180-day exclusivity period Anchen received under Hatch-Waxman by filing its ANDA before the other generics. *Id.* at 152–53 ("To the contrary, it is undisputed that the FDA could not have approved Abrika's ANDA until the end of Anchen's 180-day first-filer exclusivity period, a period that would not even start until Anchen launched its drug.").

The Court also rejects Perrigo's assertion that the *Bristol-Myers* decision, issued in 2000, is irrelevant today. (*See* ECF No. 93 at 27:19-25.) In December 2018, over a year after *In re Wellbutrin* was decided, Chief Judge Freda L. Wolfson cited to *Bristol-Myers* in a published opinion when observing "various district courts within this Circuit have declined to hold that the absence of FDA approval creates a barrier to establishing the element of causation in a patent antitrust suit." *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, 358 F. Supp. 3d 389, 398 (D.N.J. 2018) (collecting cases). The Court, therefore, finds Perrigo was not precluded from establishing antitrust standing and injury because of the absence of an FDA decision on their generic product. Moreover, the Court finds Perrigo could have demonstrated the antitrust injury necessary for its present sham litigation claim upon the filing of the AndroGel 1% Litigation and implementation of the subsequent thirty-month moratorium under Hatch-Waxman.[7] *See Warner Lambert*, 2000 WL 34213890, at *8; *Bristol-Myers*, 90 F. Supp. 2d at 545–46.

2. Accrual Date and Speculative Damages Exception

Defendants also contend "[c]ourts have long recognized that the elements of a sham litigation claim exist, and thus accrue, upon the filing of the sham lawsuit." (ECF No. 70-1 at 9 (internal quotation marks and citations omitted).) Defendants maintain "when Perrigo released all claims that had accrued arising from or related to the AndroGel 1% [Litigation] in the" Settlement Agreement, "Perrigo released its current claim that the AndroGel 1% [Litigation] was a sham. Perrigo may not now assert that released claim." (*Id.* at 14.)

[7] In addition to the thirty-month moratorium under Hatch-Waxman, Defendants argue Perrigo could have demonstrated antitrust injury through "decid[ing] between three undesirable [litigation] alternatives," the costs it incurred in defense of the AndroGel 1% Litigation, or "threatened" antitrust injury. (*See generally* ECF No. 70-1 at 11–13.) Because the Court has determined the thirty-month moratorium was sufficient to demonstrate antitrust injury, it need not address these additional arguments.

In opposition, Perrigo asserts the Court cannot conclude, as a matter of law, that its sham litigation claim accrued prior to March 27, 2012. (ECF No. 76 at 6.) Perrigo cites to an exception to the general accrual date of a sham litigation claim, known as the speculative damages exception, which "provides that '[w]here damages flowing from conduct which violate[s] the antitrust laws are uncertain at the time that the defendant engages in the challenged conduct, the cause of action for future damages accrues on the date when they are suffered.'" (*Id.* at 7 (quoting *P & M Servs., Inc. v. Gubb*, Civ. A. No. 07-12816, 2008 WL 4185903, at *6 (E.D. Mich. Sept. 8, 2008) (citing *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 401 U.S. 321, 339 (1971))).) Accordingly, Perrigo argues "the [s]peculative [d]amages [e]xception recognized in *Zenith* is fatal to Defendants' reliance on the 2012 Settlement Agreement on this pleading motion." (*Id.* at 13.)

Although the Third Circuit has not addressed the accrual question at hand, "several courts considering the issue have held that sham litigation claims accrue when the case is filed." *Med. Mut. of Ohio, Inc. v. Braintree Laboratories*, Civ. A. No. 10-604, 2011 WL 2708818, at *4 (D. Del. July 12, 2011) (collecting cases); *see also Gubb*, 2008 WL 4185903, at *5 (collecting cases) ("In general, the operative overt act for purposes of the antitrust limitations statute is the filing of the sham lawsuit."). Therefore, if the Court's inquiry ended here, it would find Perrigo's sham litigation claim accrued upon the filing of the AndroGel 1% Litigation on October 31, 2011, before the Settlement Agreement's Effective Date.

However, as Perrigo correctly notes (ECF No. 76 at 7), there are two exceptions to this general accrual rule that toll the Sherman Act's statute of limitations. Relevant here, the speculative damages exception provides, "even if injury and a cause of action have accrued as of a certain date, future damages that might arise from the conduct sued on are unrecoverable if the fact of their accrual is speculative or their amount and nature unprovable." *Zenith*, 401 U.S. at 339. "In these instances, antitrust causes of action for future damages 'will accrue only on the date [the

damages] are suffered; thereafter the plaintiff may sue to recover them at any time within four years from the date they were inflicted.'" *Meijer, Inc. v. 3M*, Civ. A. No. 04-5871, 2005 WL 1660188, at *5 (E.D. Pa. July 13, 2005) (quoting *Zenith*, 401 U.S. at 339); *see also Lender's Serv., Inc. v. Dayton Bar Ass'n*, 758 F. Supp. 429, 442 (S.D. Ohio 1991) ("However, where future damages are too speculative to be proved, a cause of action accrues on the date they are suffered.").

There is an important distinction, however, between "uncertain damages, which prevent recovery" and therefore toll the statute of limitations, and "uncertain extent of damage, which does not prevent recovery." *Pace Indus., Inc. v. Three Phoenix Co.*, 813 F.2d 234, 240 (9th Cir. 1987) (citation omitted); *see also Charlotte Telecasters, Inc. v. Jefferson-Pilot Corp.*, 546 F.2d 570, 573 (4th Cir. 1976). "The former denotes failure to establish an injury, while the latter denotes imprecision with regard to the scope or extent of the injury." *Pace*, 813 F.2d at 240. "The question of whether there is a right to recovery is not to be confused with the difficulty in ascertaining the scope or extent of the injury." *Id.*

To demonstrate the speculative nature of their damages as of the Effective Date, Perrigo cites to the uncertainty concerning: (1) "the issuance and timing of FDA approval of Perrigo's generic 1% AndroGel"; (2) "whether the FDA would issue any 'TE' rating and, if so, whether the TE rating would be 'AB' or a lower rating such as 'BX'"; (3) "how Perrigo might respond if it did not receive the AB rating it requested"; and (4) "how Perrigo would have fared financially if it decided to launch a product without an AB rating." (ECF No. 76 at 8.) These factors, however, relate to the *scope* of Perrigo's damages, not whether Perrigo had, in fact, suffered an injury or right to recovery. Perrigo's Complaint alleges, at the time the AndroGel 1% Litigation commenced, Defendants were aware their lawsuit was both objectively and subjectively baseless. (ECF No. 1 ¶¶ 69, 72.) Perrigo first asserts Defendants were objectively aware because "[n]either the Teva [generic] product nor the Perrigo [generic] product contained the penetration enhancer

isopropyl myristate, the only penetration enhancer claimed in the '894 [P]atent." (*Id.* ¶ 70.) According to Perrigo, "AbbVie and Besins could not purposely surrender claims to all penetration enhancers except one," *i.e.*, isopropyl myristate, "in order to obtain the patent in the first instance and then claim infringement when a competitor used an enhancer they had deliberately surrendered." (*Id.* ¶ 71.) Perrigo, therefore, contends "[n]o reasonable person in Defendants' position could have realistically expected to prevail on the merits of their patent infringement claims against Teva and Perrigo." (*Id.*) Moreover, Perrigo asserts Defendants were subjectively aware their lawsuit was baseless because: (1) they had previously decided not to sue Perrigo for patent infringement because the products contained different formulations (*id.* ¶ 73); (2) "[t]he individuals who made the decision on AbbVie's behalf to file [the] objectively baseless lawsuits against Perrigo and Teva were four experienced patent attorneys" (*id.* ¶ 74); and (3) Defendants' "decision-makers . . . were aware of the paragraph IV notices sent by Perrigo and Teva, which made it clear that their respective products did not contain the single penetration enhancer claimed in the '894 [P]atent" (*id.* ¶ 75).

In *Gubb*, the district court held the speculative damages exception did not apply to a sham litigation claim, in part, because, at the time the alleged sham lawsuit was filed, the plaintiff had already asserted the patent in question was invalid. *Gubb*, 2008 WL 4185903, at *6. According to the court, "[t]here [were] no facts that came to light *at a later date* which revealed the alleged 'sham' nature of the litigation." *Id.* (emphasis added). Similarly, here, at the time of the AndroGel 1% Litigation, Perrigo had twice asserted its generic product did not infringe upon the '894 Patent. (ECF No. 1 ¶¶ 36, 53.) Moreover, in both of its paragraph IV notices to Defendants, Perrigo maintained "the prosecution history of the '894 [P]atent precluded any valid infringement claim under the doctrine of equivalents." (*Id.* ¶ 54; *see also id.* ¶ 36.) Coupled with Solvay and Unimed's previous 2009 press release stating "the companies had decided not to file a patent infringement

suit against Perrigo" because "the Perrigo [generic] product contains a different formulation than the formulation protected by the AndroGel patent" (*id.* ¶ 38 (internal quotation marks omitted)),[8] the Court is unable to discern how, at the time the AndroGel 1% Litigation commenced, Perrigo's damages were so uncertain as to preclude the establishment of an injury or right to recovery. Moreover, despite the uncertainty surrounding if, when, and how the FDA would approve the Perrigo product, and how this decision would affect Perrigo's future decisions and financial standing (*see* ECF No. 76 at 8), "[t]he fact that a plaintiff's injuries 'have a rippling effect into the future only establishes' [its] possible entitlement to future damages and does not eliminate the requirement of bringing suit within four years of an overt act which causes injury." *Lender's Serv.*, 758 F. Supp. at 442 (quoting *Peck v. Gen. Motors Corp.*, 894 F.2d 844, 849 (6th Cir. 1990)).

Accordingly, the Court finds, based upon the undisputed factual allegations of this matter, the speculative damages exception set forth in *Zenith* does not apply to Perrigo's sham litigation claim. The claim, therefore, accrued at the time the AndroGel 1% Litigation commenced on October 31, 2011. There is also no "genuine question as to whether [Perrigo] signed the [Settlement Agreement and release] knowingly and voluntarily." *Geraghty v. Ins. Servs. Office, Inc.*, Civ. A. No. 08-1203, 2009 WL 1025544, at *4 (D.N.J. Apr. 16, 2009) (citing, *inter alia*, plaintiff's "highly sophisticated education," "large role in negotiation the terms," and representation by an expert attorney, as well as the clarity of the agreement); *see also Cooper*, 977 F. Supp. at 312 ("The record shows that [plaintiff] read, understood and consented to the terms of the . . . Release, therefore the release is presumptively valid."). Nor does Perrigo claim (*see generally* ECF No. 76) an exception to the "presumptive conclusion" that the release is valid exists because of "fraud, misrepresentation, overreaching by the releasee, incapacity of the releasor

[8] "Besins also determined that it was 'standing down' from bringing an infringement suit but did not join in the Solvay press release or issue its own public announcement." (*Id.*)

affecting [its] ability to understand the release, or any other equitable ground." *Cooper*, F. Supp. at 313 (citations omitted). Because the Court finds the release to be valid, and because it is undisputed it released the parties from any and all claims related to the AndroGel 1% Litigation that accrued prior to March 27, 2012 (ECF No. 70-6 § 7; *id.* at 14; *see also* ECF No. 70-1 at 3–4; ECF No. 76 at 1), Perrigo is barred from now setting forth a claim that the same litigation was a sham. *See Raroha v. Earle Fin. Corp.*, 220 A.2d 107, 109 (N.J. 1966) ("It may be that plaintiff's injuries are now more serious than he believed them to be when he signed the release. However, . . . it is the law of this State that the release is binding and that the releasor will be held to the terms . . . he willingly and knowingly entered."); *see also Geraghty v. Ins. Servs. Office, Inc.*, 369 F. App'x 402, 406 (3d Cir. 2010) ("Under New Jersey law, the phrase 'any and all' [in a release] allows for no exception." (internal quotation marks and citations omitted)).[9]

B. Unclean Hands

Perrigo also argues, even if the Settlement Agreement's release is otherwise enforceable, Defendants should be barred from enforcing the release pursuant to the doctrine of unclean hands. (ECF No. 76 at 15.) Perrigo argues the doctrine of unclean hands applies "based on much of the same evidence that led the courts in the FTC litigation to conclude that Defendants filed sham patent infringement litigation against Perrigo in furtherance of their monopolistic conduct." (*Id.*)[10]

[9] Defendants also argue Perrigo released its present claim through a release within a 2015 settlement agreement related to AndroGel 1.62%, a more concentrated version of AndroGel 1% covered by the '894 Patent. (ECF No. 70-1 at 14.) Defendants argue "[t]here can be no question the claim here had accrued by 2015," "[n]or is there any legitimate question about whether Perrigo released its AndroGel 1% sham claim in the 2015 settlement agreement." (*Id.*) Because the Court finds the 2012 Settlement Agreement dispositive it will not address Defendants' arguments related to the 2015 settlement agreement.

[10] The FTC litigation refers to an action the Federal Trade Commission ("FTC") brought against Defendants in the Eastern District of Pennsylvania, Civ. A. No. 14-5151. (ECF No. 1 ¶ 93.)

The burden, however, on a party seeking to invoke the doctrine is "extremely high" and requires the application of a clear and convincing evidentiary standard. *Connelly Constr. Corp. v. Travelers Cas. & Sur. Co. of Am.*, Civ. A. No. 16-555, 2018 WL 263316, at *12 (E.D. Pa. Jan. 2, 2018), *aff'd* 788 F. App'x 122 (3d Cir. 2019) (citing *Citizens Fin. Grp., Inc. v. Citizens Nat. Bank of Evans City*, 383 F.3d 110, 129 (3d Cir. 2004)). "Moreover, the allegedly improper conduct must have occurred 'in the very controversy' at hand, and the party against whom the doctrine is being employed must have 'so conducted himself as to shock the moral sensibilities of the judge.'" *Id.* (quoting *Gaudiosi v. Mellon*, 269 F.2d 873, 881 (3d Cir. 1959)). Here, Perrigo maintains it "was not obliged to raise the issue of unclean hands in its complaint in anticipation of Defendants asserting the 2012 release as an affirmative defense." (ECF No. 76 at 15.) Perrigo, however, cites no legal authority for this assertion. Furthermore, the doctrine requires a "close nexus between the 'unclean hands' and the specific issue in dispute," *Connelly*, 2018 WL 263316, at *12; *see also Pharmacia Corp. v. GlaxoSmithKline Consumer Healthcare, L.P.*, 292 F. Supp. 2d 594, 610 (D.N.J. 2003), but Perrigo invokes the doctrine against the actual filing of the AndroGel 1% Litigation, *not* Defendants' conduct as it relates to the Settlement Agreement and release. *See Connelly*, 2018 WL 263316, at *12 ("The 'nexus' requirement dictates that the allegedly improper conduct must have taken place with respect to the execution of the waivers and change order documents, rather than in the context of [defendant's] relationship with [plaintiff] writ large.").

The Court, therefore, finds Perrigo has failed to meet its burden of demonstrating Defendants acted with unclean hands. Having determined the parties' Settlement Agreement and

release barred Perrigo's current sham litigation claim, Defendants' Motion for Judgment on the Pleadings is **GRANTED** and Perrigo's Complaint is **DISMISSED WITH PREJUDICE**.[11]

IV. CONCLUSION

For the reasons set forth above, Defendants' Motion for Judgment on the Pleadings (ECF No. 70) is **GRANTED**. An appropriate order follows.

Date: September 30, 2021

/s/ Brian R. Martinotti
HON. BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE

[11] *See, e.g.*, *JRJ Hosp., Inc. v. Twin City Fire Ins.*, Civ. A. No. 20-13095, 2021 WL 3561356, at *7 (D.N.J. Aug. 12, 2021) (granting defendant's motion for judgment on the pleadings and dismissing amended complaint with prejudice where "there [was] no additional discovery or amended pleadings that [would have] change[d] the court's reading of the plain language of the policy").